~~APPROVED~~ DRAFT PA CRITERIA

Initial Approval: January 10, 2018
Revised Dates: October 9, 2019; April 10, 2019;
October 10, 2018;
July 11, 2018; April 11, 2018

CRITERIA FOR PRIOR AUTHORIZATION

Opioid Products Indicated for Pain Management

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage~~PROVIDER GROUP Pharmacy~~

MANUAL GUIDELINESAll dosage forms of the following drugs require prior authorization:

Long-Acting Opioids:

Includes both brand and generic versions of the listed products unless otherwise noted:
Buprenorphine (Butrans, Belbuca)
Fentanyl transdermal (Duragesic)
Hydrocodone extended-release (Zohydro ER, Hysingla ER, Vantrela ER)
Hydromorphone extended-release (Exalgo)
Methadone
Morphine controlled-release/extended-release (Kadian ER, Avinza, MS Contin, Oramorph, Arymo ER)
Morphine/Naltrexone (Embeda)
Oxycodone extended-release (OxyContin)
Oxycodone extended-release (Xtampza ER)
Oxycodone/Naloxone (Targiniq ER)
Oxycodone/Naltrexone (Troxyca ER)
Oxymorphone extended-release (generic non-crush resistant)
Oxymorphone extended-release (Opana ER-crush resistant)
Tapentadol extended-release (Nucynta ER)
Tramadol extended-release (Ultram ER, Ryzolt)

Short-Acting Opioids:

Includes both brand and generic versions of the listed products unless otherwise noted: (All salt forms, single and combination ingredient products, and all brand and generic formulations of the following):
Benzhydrocodone
Butorphanol
Codeine
Dihydrocodeine
Fentanyl
Hydrocodone
Hydromorphone
Levorphanol Tartrate
Meperidine
Morphine
Opium
Oxycodone
Oxymorphone
Pentazocine/Naloxone
Tapentadol
Tramadol

1. CRITERIA FOR OPIOID USE IN DIAGNOSIS OF CANCER, SICKLE CELL DISEASE, HOSPICE/PALLIATIVE CARE, OR THOSE RESIDING IN AN ASSISTED OR CUSTODIAL CARE ENVIRONMENT

- Trans-mucosal Immediate Release Fentanyl (TIRF) products are only approved for patients with a diagnosis of cancer.
- Fentanyl patches are only approved for patients with a diagnosis of cancer or palliative care related pain.
- Methadone is only approved for diagnosis of terminal cancer pain.
- Prescriber must attest that they are enrolled in the REMS program to prescribe for TIRF products.
- Patient must fall into one of the following categories:
    - Patient is being treated for pain related to active cancer diagnosis.
    - Patient is being treated for sickle cell disease.
    - Patient is receiving hospice or palliative care.
    - Patient is residing in an assisted or custodial care environment and medication is facility administered.

Approval Duration: 12 months

2. CRITERIA FOR OPIOID USE IN NON-CANCER, NON-SICKLE CELL DISEASE, NON-HOSPICE/PALLIATIVE CARE FOR HOSPITAL DISCHARGE, POST-SURGICAL, OR ACUTE TRAUMA (Methadone and fentanyl products are not covered for acute pain).

- Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program (PDMP) a.k.a K-TRACS.
- Prescriber must attest that the patient has been counseled on potential respiratory depression.
    - Cumulative opioid dose must not exceed 90 MME per day.
    - Total day supply for the requested medication must not exceed 21 days (3 weeks).

Approval Duration: 3 weeks

3. CRITERIA FOR OPIOID USE IN NON-CANCER, NON-SICKLE CELL DISEASE, NON-HOSPICE/PALLIATIVE CARE FOR ACUTE PAIN (For these PA requests, acute pain is defined as patients with < 90 days of opioid medication in the past 120 days. Methadone and fentanyl products are not covered for acute pain)

- No prior authorization is required for prescriptions equal to or for no more than a cumulative 14 day supply of opioids in the last 60 days within allowed limits.
    - Maximum of 7 day supply is allowed per fill.
    - Cumulative opioid dose must not exceed 90 MME per day.
    - Drug must not exceed maximum FDA approved dosage.
    - Drug requested must not be a long-acting opioid.
- Prior authorization is required to exceed 14 day supply of opioid medication in last 60 days (must meet all of the following):
    - Patient has attempted treatment with at least 2 non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) in the last 90 days, unless contraindicated.
    - Cumulative opioid dose must not exceed 90 MME per day or maximum FDA approved dosage.
    - Drug requested is not a long-acting opioid.
    - Prescriber attests to the following:
        - Non-pharmacological treatment has been tried and/or is currently being used (e.g., exercise, cognitive behavior therapy, or interventional treatment)
        - Prescriber has reviewed controlled substance prescriptions in the Prescription Drug Monitoring Program (PDMP) a.k.a K-TRACS.
        - Treatment duration and goals are defined with the patient and in the medical record.
        - Patient has been screened for substance abuse/opioid dependence.

- If patient is concurrently on a CNS depressant (e.g., benzodiazepines), prescriber has reviewed and will address the increased risk of respiratory depression with the patient.
- Patient has been screened for depression or other mental health illness.
    - If patient is positive for depression, patient is receiving either pharmacological or nonpharmacological treatment.

Renewal Criteria:

- Attempting to taper dose/frequency **or**
- Documentation in medical record the reason for not tapering the dose/frequency

Approval Duration: 30 days; Maximum of 2 renewals (90 days total, not including the initial 14 days of treatment before PA is required)

4. **CRITERIA FOR OPIOID USE IN NON CANCER, NON SICKLE CELL DISEASE, NON HOSPICE/PALLIATIVE CARE FOR CHRONIC PAIN**
(For these PA requests, chronic pain is defined as patients with ≥90 days of opioid medication in the past 120 days Methadone and fentanyl products are not covered for chronic pain)

- Prior authorization is required to exceed 90 day supply of opioid claims (must meet all of the following):
    - Patient has attempted treatment with at least 2 non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants), unless contraindicated.
        - Patient must not be chronically taking more than one long-acting & one short-acting opioid analgesic concurrently.
    - Prescriber attests to the following:
        - Non-pharmacological treatment has been tried and/or is currently being used. (e.g., exercise, cognitive behavior therapy, or interventional treatment).
        - Prescriber has reviewed controlled substance prescriptions in PDMP (K-TRACS).
    - Documentation of treatment duration and treatment goals to include:
        - Rationale for not tapering and discontinuing opioid.
        - Patient has a pain management/opioid agreement with the prescriber.
        - Patient has/will have random urine drug screens as part of their on-going therapy with opioids.
        - If patient is concurrently on a CNS depressant (e.g., benzodiazepines), prescriber has reviewed and will address the increased risk with respiratory depression with the patient.
        - Patient has screened for depression or other mental health illness.
            - If patient is positive for depression, patient is receiving either pharmacological or nonpharmacological treatment.
    - Patient has been screened for substance abuse/opioid dependence.
    - If dose exceeds 90 MME per day, prescriber must attest to one of the following:
        - Dose reduction has occurred since previous approval.
        - Documentation that a dose taper has been attempted within the past 6 months and was not successful.
    - If request is for a long-acting opioid, must meet the following:
        - Patient must have a documented history of failure, contraindication or intolerance to a trial of at least two preferred short-acting opioids.
        - Patient must have received a short-acting opioid for greater than 30 days in the last 60 days.
        - Trial and failure of at least two preferred long-acting opioids are required before the use of a non-preferred unless there is intolerance or contraindications.
- If none of the above criteria are met, a one-time, one-month override is allowed for tapering.

Initial Approval Duration: 3 months

- Renewal Authorization Criteria for Chronic Pain
  - All narcotic analgesics are written by a single prescriber or practice.
  - Documentation of treatment duration and treatment goals.
  - Prescriber provides rationale supporting inability to discontinue opioid therapy.
  - Patient will not be maintained on more than one long-acting & one short-acting opioid analgesics, concurrently.
  - Patient has a pain management/opioid agreement with the prescriber (excluding patients in a long-term care facility).
  - Prescriber has reviewed controlled substance prescriptions in PDMP (KTRACS).
  - Patient has/will have random urine drug screens as part of their on-going therapy with opioids (excluding patients in a long-term care facility)
  - If the current dose exceeds 90 MME/day, ONE of the following criteria must be met:
    - Dose reduction has occurred since previous approval.
    - Documentation that a dose taper has been attempted within the past 6 months and was not successful.
    - Provider attests that a dose taper is not clinically appropriate for this patient.

Renewal Approval Duration: 12 months

NOTES:

GENERAL CRITERIA FOR OPIOID MEDICATION USE:

- Initial use max of 7-day fills (cumulative 14 day supply in 60 days) is allowed before PA will be required.
- Ninety percent (90%) of medicine must be used prior to a refill unless a PA for early refill is approved.
- Prescriber must attest to reviewing K-TRACS prior to writing every new opioid prescription.
- Prescriber should calculate total MME per day for concurrent opioid medications.
- Initial use of immediate-release opioids is required before use of ER/LA opioids.
- Provider attests to limiting and avoiding where possible the concurrent use of CNS depressants, especially benzodiazepines, when prescribing opioids.
- Before starting & periodically, an evaluation of risk factors for opioid related harms should be done.
- Non-opioid ancillary treatments (e.g., NSAIDs, acetaminophen, antidepressants) and non-pharmacological treatments should be tried first unless contraindicated.
- Prescriber has screened patient for depression and substance use disorder.
- New dosage forms or strengths to agents listed can be added as they become available.
- Drug must not exceed maximum FDA approved dosage.
- Physician must consider use of opioids and Neonatal Opioid Withdrawal Syndrome if patient is pregnant.

DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

_____ _____

DATE **DATE**

TABLE 1.: Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors

Type of Opioid (strength units)	MME Conversion Factor
Benzhydrocodone (mg)[11]	1.2
Buprenorphine film/tablet[3] (mg)	30
Buprenorphine patch[4] (mcg/hr)	12.6
Buprenorphine film (mcg)	0.03
Butorphanol (mg)	7
Codeine (mg)	0.15
Dihydrocodeine (mg)	0.25
Fentanyl buccal or SL tablets, or lozenge/troche[5] (mcg)	0.13
Fentanyl film or oral spray[6] (mcg)	0.18
Fentanyl nasal spray[7] (mcg)	0.16
Fentanyl patch[8] (mcg)	7.2
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Methadone[9] (mg)	Methadone[9] (mg)
>0, <= 20	4
>20, <=40	8
>40, <=60	10
>60	12
Morphine (mg)	1
Opium (mg)	1
Oxycodone (mg)	1.5
Oxymorphone (mg)	3
Pentazocine (mg)	0.37

Tapentadol[10] (mg)	0.4
Tramadol (mg)	0.1

1 The MME conversion factor is intended only for analytic purposes where prescription data is used to calculate daily MME. It is to be used in the formula: Strength per Unit X (Number of Units/ Day Supply) X MME conversion factor = MME/Day. This value does not constitute clinical guidance or recommendations for converting patients from one form of opioid analgesic to another. Please consult the manufacturer's full prescribing information for such guidance. Use of this file for the purposes of any clinical decision-making warrants caution.

2National Center for Injury Prevention and Control. CDC compilation of benzodiazepines, muscle relaxants, stimulants, zolpidem, and opioid analgesics with oral morphine milligram equivalent conversion factors, 2016 version. Atlanta, GA: Centers for Disease Control and Prevention; 2016. Available at https://www.cdc.gov/drugoverdose/media/. For more information, send an email to Mbohm@cdc.gov.

3 Buprenorphine formulations with a FDA approved indication for Medication Assisted Treatment (MAT) are excluded from Medicare's Overutilization Monitoring System's opioid overutilization reporting.

4 The MME conversion factor for buprenorphine patches is based on the assumption that one milligram of parenteral buprenorphine is equivalent to 75 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24 hour day. Example: 5 micrograms/hour buprenorphine patch X 24 hours = 120 micrograms/day buprenorphine = 0.12mg/day = 9 mg/day oral MME. In other words, the conversion factor not accounting for days of use would be 9/5 or 1.8 However, since the buprenorphine patch remains in place for 7 days, we have multiplied the conversion factor by 7 (1.8 X 7= 12.6) In this example, MME/day for four 5 microgram/hour buprenorphine patches dispensed for use over 28 days would work out as follows: Example: 5 microgram/ hour buprenorphine patch X (4patches/28days) X 12.6 = 9 MME/day. Please note that because this allowance has been made based on the typical dosage of one buprenorphine patch per 7 days, you should first change all Day Supply in your prescription data to follow this standard, i.e. Day Supply for buprenorphine patches = # patches X 7.

5 The MME conversion factor for fentanyl buccal tablets, sublingual tablets, and lozenges/troche is 0.13. This conversion factor should be multiplied by the number of micrograms in a given tablet or lozenge/troche.

6 The MME conversion factor for fentanyl film and oral spray is 0.18. This reflects a 40% greater bioavailability for films compared to lozenges/tablets and 38% greater bioavailability for oral sprays compared to lozenges/tablets.

7 The MME conversion factor for fentanyl nasal spray is 0.16, which reflects a 20% greater bioavailability for sprays compared to lozenges/tablets.

8 The MME conversion factor for fentanyl patches is based on the assumption that one milligram of parenteral fentanyl is equivalent to 100 milligrams of oral morphine and that one patch delivers the dispensed micrograms per hour over a 24 hour day. Example: 25 micrograms/ hour fentanyl patch X 24 hours = 600 micrograms /day fentanyl = 60 milligrams/day oral morphine milligram equivalent. In other words, the conversion factor not accounting for days of use would be 60/25 or 2.4 However, since the fentanyl patch remains in place for 3 days, we have multiplied the conversion factor by 3 (2.4 X 3 = 7.2) In this example, MME/day for ten 25 micrograms/hour fentanyl patches dispensed for use over 30 days would work out as follows: Example: 25 microgram/hour fentanyl patch X (10 patches/30 days) X 7.2 = 60 MME/day. Please note that because this allowance has been made based on the typical dosage of one fentanyl patch per 3 days, you should first change all Day Supply in your prescription data to follow this standard, i.e., Day Supply for fentanyl patches = # of patches X 3.

9 https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

10 Tapentadol is a mu receptor agonist and norepinephrine reuptake inhibitor. Oral MMEs are based on degree of mu-receptor agonist activity, but it is unknown if this drug is associated with overdose in the same dose-dependent manner as observed with medications that are solely mu receptor agonists.

11 MME conversion factor for this medication has been determined based on information provided in the manufacturer label stating that 6.12 mg of benyhydrocodone is equivalent to 7.5 mg of hydrocodone bitartrate

TABLE 2a.

SA Exceptions to MME Limits	
Drug	**Max Dose per day**
Butorphanol Nasal Spray (Stadol)	5mg/day
Codeine	360mg/day
Codeine/APAP (Tylenol with Codeine #3, Tylenol with Codeine #4)	360mg/day
Codeine/Butalbital/APAP/Caffeine (Fioricet with Codeine)	360mg/day
Codeine/Butalbital/ASA/Caffeine (Fiorinal with Codeine, Ascomp with Codeine)	360mg/day
Dihydrocodeine/APAP/Caffeine (Trezix, Dvorah, Panlor)	160mg/day
Dihydrocodeine/ASA/Caffeine (Synalgos)	160mg/day
Tapentadol (Nucynta)	700mg/day
Tramadol (Ultram)	400mg/day
Tramadol/APAP (Ultracet)	300mg tramadol (PPI)
Meperidine (Demerol)	600 mg/day
Oxycodone/Ibuprofen (Combunox)	20mg/day

Oxycodone/ASA (Percodan)	58.02mg/day
Pentazocine/Naloxone	600mg/day

Table 2b.

LA Exceptions to MME Limits		
Drug	Max Dose/Day	Dose Optimization/Other Limits
Buprenorphine (Butrans®)	480mcg	1 unit/7d
Buprenorphine Buccal Film (Belbuca®)	1800mcg	2 units/day
Tramadol ER (Ultram ER®)	300mg	1 unit/day
Tramadol ER (Conzip®)	300mg	1 units/day
Tramadol ER (Ryzolt®)	300mg	2 units/day

TABLE 3a.

Short-Acting Opioid MME Limits		
Drug	MME Conversion factor	90 MME/Day Dose
Benzhydrocodone/APAP (Apadaz)	1.2**	75 mg
Fentanyl (Actiq)	0.13	600mcg*
Fentanyl (Fentora)	0.13	700mcg*
Fentanyl (Abstral)	0.13	700mcg*
Fentanyl (Lazanda)	0.16	600mcg*
Fentanyl (Subsys)	0.18	500mcg
Hydrocodone/APAP (Lortab, Hycet, Zamicet, Xodol, Verdrocet, Vicodin, Lorcet, Norco, Vicodin ES, Lorcet Plus, Lorcet HD, Vicodin HP, Maxidone)	1	90mg
Hydrocodone/Ibuprofen	1	90
Hydromorphone (Dilaudid)	4	22.5mg
Levorphanol (Levo-Dromoran)	11	8mg*
Meperidine/Promethazine	0.1	600 mg
Morphine IR	1	90mg
Morphine (Roxanol)	1	90mg
Morphine/Naltrexone	1	90 mg
Opium/Belladonna Rectal	1	4 doses per day
Opium Tincture	1	9 mL (90 mg)
Oxymorphone (Opana)	3	30mg
Oxycodone (Roxicodone)	1.5	60mg
Oxycodone (Roxybond)	1.5	60mg
Oxycodone (Oxaydo)	1.5	60mg
Oxycodone/APAP (Primlev, Endocet, Percocet, Roxicet)	1.5	60mg
Oxycodone (Roxicodone Intensol)	1.5	60mg

*MME for these medication have been rounded due to dosage form limitations. Actiq 90 MME rounded down from 692 mcg; (smallest dosage form is 200 mcg). Fentora and Abstral 90 MME rounded up from 692 mcg; (smallest dosage from is 100 mcg). Lazanda 90 MME rounded up from 563 mcg; (Smallest dosage from is 100mcg/actuation).

**MME conversion factor for this medication has been determined based on information provided in the manufacturer label stating that 6.12 mg of benyhydrocodone is equivalent to 7.5 mg of hydrocodone bitartrate

Table 3b.

Long Acting Opioid Dose Limits			
Drug	MME Conv. Factor	90 MME/Day Dose	Dose Optimization/Other Limits
Fentanyl (Duragesic®)	2.4/day 7.2/Q3 days	900 mcg (37.5mcg/hr. patch)	1 unit/2days
Hydrocodone ER (Hysingla ER®, Vantrela ER®, Zohydro ER®)	1	90mg	Hysingla ER: 1 units/day Zohydro ER and Vantrela ER: 2 units/day
Hydromorphone (Exalgo®)	4	22.5mg	1 unit/day
Morphine Sulfate ER (Arymo ER®, Avinza®, Kadian ER®, MS Contin®, Oramorph®)	1	90mg	MS Contin, Kadian ER, Oramorph, and Arymo ER 3 units/day Avinza: 2units/day
Morphine/Naltrexone (Embeda®)	1	90mg	2 units/day
Morphine (MorphaBond ER®)	1	90mg	2 units/day
Oxycodone CR (Oxycontin®)	1.5	60mg	3 units/day
Oxycodone (Xtampza ER®)	1.665 .	54mg	2 units/day
Oxycodone/Naloxone (Targiniq ER®)	1.5	60mg	2 units/day
Oxycodone/Naltrexone (Troxyca ER®)	1.5	60mg	2 units/day
Oxymorphone ER (Opana ER®)	3	30mg	2 units/day
Tapentadol ER (Nucynta ER®)	0.4	225mg	2 units/day
(oxycodone/acetaminophen) Xartemis XR®	1.5	60mg	7ds/yr. = 28tabs/365d

*Opana ER® use is not recommended due to FDA warnings about abuse potential.
*Subutex®, Suboxone®, Zubsolv®, Zubsolv SL®, Suboxone SL®, and Bunavail®, and Subutex® reserved for Medication Assisted Treatment (MAT) for Opioid Dependence. Methadone also reserved for MAT.

*Conversion factors and doses were determined using Facts and Comparisons, CMS guidelines, and verified with opioid MME calculators.
References: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-April-2017.pdf

References: https://www.easycalculation.com/medical/opioid-conversion-calculator.php
References: http://www.agencymeddirectors.wa.gov/calculator/dosecalculator.htm
References: https://kempharm.com/wp-content/uploads/2018/03/NDA-208653-Final-Label-PI-0167-01-R.02-18.pdf